

REMARKS

Claims 1, 4-6, 9 and 10 are in the application.

Claims 1, 4-6, 9 and 10 Are Patentable Under 35 U.S.C. § 103

On page 3 of the Office Action, the Office rejects Claims 1, 4, 6, and 9 under 35 U.S.C. §103 as allegedly being unpatentable over Fujimoto Eiki *et al.* (11-023573, English Translation) in view of Dosa *et al.* (Immunology, 1979, 38, pages 509-517) and further in view of Scherr (US Patent #4,096,138). On page 5 of the Office Action, the Office rejects Claims 5 and 10 under 35 U.S.C. 103(a) as being unpatentable over Fujimoto Eiki *et al.* (11-023573, English Translation) in view of Dosa *et al.* (Immunology, 1979, 38, pages 509-517) and further in view of Scherr (US Patent #4,096,138) as applied to Claims 1, 4, 6, and 9 above, and further in view of Nakase *et al.* (JP 48019719 Abstract Only).

Applicants respectfully disagree. The Examiner admits, “(a)lthough Fujimoto Eiki *et al.* disclose BSA denaturation by heat (thermal), they are silent with respect to protease treatment (pepsin digest) to produce fragmented BSA.” Page 3, lines 12-14, Office Action. Under current law, it is mandatory that the Office explicitly identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR International Co. v. Teleflex Inc.*, 550 U.S. _____ (2007). The Office fails to satisfy this burden, at least in part because it is impossible to state a reason for combining elements that are not disclosed. It is readily apparent that the thermally denatured albumin disclosed in Fujimoto Eiki *et al.* requires that the denatured albumin should be used in the polymerized or aggregated form to inhibit nonspecific reactions. Paragraphs [0023], [0025], [0039], and [0042] of the enclosed partial English translation of Fujimoto Eiki *et al.* The increase in molecular weight of albumin, such as BSA, is essential to inhibit nonspecific reactions

according to the reference as cited by the Examiner. A person having ordinary skill in the art would not have the rationale, motivation or capability of substituting the protease-treated fragmented BSA for the thermally denatured albumin by the teaching of Dosa *et al.* to attain the Applicants' invention. The Office failed to meet its burden to establish a *prima facie* case of obviousness at least because there is not a scintilla of evidence of a rationale or motivation to use the protease-treated fragmented BSA in order to obtain Applicants' invention.

Withdrawal of the obviousness rejection is therefore respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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